

NOV 28 2008

See attached form for additional information.

Interagency Report Control No. *for*

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 57-R-0005
CUSTOMER NUMBER: 900

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

University of Georgia
Vp For Rsch, Boyd Grad Rsch Ctr Rm 608
Athens, GA 30602

Telephone: (706) -542-~~5983~~ 5933

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	2	27	200		227
5. Cats		20	119		139
6. Guinea Pigs		26			26
7. Hamsters		72			72
8. Rabbits		97			97
9. Non-human Primates		8			8
10. Sheep					
11. Pigs	1	290	63		353
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

DATE SIGNED

11/26/08

(OCT 88), which is obsolete.)

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 57-R-0005
CUSTOMER NO. 900

FORM APPROVED
OMB NO. 0579-0036

**CONTINUATION SHEET FOR ANNUAL REPORT
OF RESEARCH FACILITY**
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) University of Georgia
VP For Research, Boyd Grad Rsch Ctr, Rm 608
Athens, GA 30602

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Cow		10	16	52	78
Goat			13		13
Horse		10	24		34
Deer		3		6	9
Degu				21	21
Ferret		2		49	51
Gerbil			492		492
Iguana		12			12
Opossum		15			15
Opossum-short tail		6			6
Raccoon			6		6
Nine Banded Armadillo		1			1

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

AL OFFICIAL

DATE SIGNED

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

11/26/08

Column E Explanation

1. **Registration Number:** 57-R-0005 (The University of Georgia, Office of the Vice President for Research)
2. **Number of animals used in this study:** 52
3. **Species of animals used in this study:** bovine
4. **Explanation of the procedure producing pain and/or distress.**

Bovines were infected with VSNJV via infected black fly bite or by contact with infected bovines. Animals infected via black fly bite were sedated (xylazine) during the infection stage. Animals were sampled (serum, oral, nasal, and tonsil swabs) on post-infection days 1-5 or longer if virus shedding lasted longer than 5 days. Bovines were euthanized at 12 days post infection.

5. **Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

Our objectives are to determine the extent to which clinical outcome and extent and source of virus shedding in VSNJV infected cattle and horses are dependent on virus strain and route of inoculation and to define the potential for virus transmission by insects and by animal-to-animal contact in relation to livestock infection with epidemic VSNJV strains. Attempts to alleviate pain or discomfort would likely interrupt the natural progression of clinical signs and interfere with the study. We used endpoint score sheets as guidance to determine when animals should be euthanized rather than maintained in a progressively ill condition.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CRF) title number and the specific section number (e.g., APHIS, 9 CFR 113,102):**

Agency _____ CFR _____

Column E Explanation

1. **Registration Number:** 57-R-0005 (The University of Georgia, Office of the Vice President for Research)
2. **Number of animals used in this study:** 6
3. **Species of animals used in this study:** white-tailed deer
4. **Explanation of the procedure producing pain and/or distress.**

White-tailed deer were inoculated subcutaneously and intradermally with epizootic hemorrhagic disease virus serotype 6 that had been propagated in BHK cells; deer were tranquilized for this procedure. This was done to determine susceptibility of white-tailed deer to this virus and the type of disease that would develop. This virus was suspected to cause high fever, coagulation defects, hemorrhage, pulmonary edema, and laminitis. Animals were observed three times a day (approximately 8 am, 1 pm, 6 pm); temperatures taken on post inoculation days 0,3,5,7,10,12, and 19, and blood collected on post inoculation days 0,3,5,7, 10, 12 and 19 to do coagulation assays, platelets counts, CBCs, and several biochemistry analyses. Deer were tranquilized for body temperature evaluation and to draw blood. Deer were to be euthanized if they met pre-established endpoint criteria (included with original AUP). Two deer were euthanized on day 12 because they developed unanticipated CNS signs that were not part of our scoring system. The white-tailed deer, along with samples collected, will contribute to the overall scientific knowledge on the pathogenesis and virulence of this new (at least to the US) epizootic hemorrhagic disease virus in white-tailed deer.

5. **Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

Nothing is known about the pathogenesis and virulence of this new epizootic hemorrhagic disease serotype in white-tailed deer, however, other serotypes of this virus are a major cause of disease in white-tailed deer. The goal of this study was to characterize the clinical signs, laboratory clinical parameter alterations, viral shedding, and gross and microscopic tissue alterations associated with the virus. The treatment of overtly sick animals would prevent documentation of clinical disease and/or lesions, if any.

A literature search was conducted for refinement, replacement, or reduction opportunities in compliance with USDA policy #12. The original AUP contains the databases searched originally. An additional search using MEDLINE, EMBASE, and the world-wide web (GOOGLE) using key words white-tailed deer, epizootic hemorrhagic disease and virus, bluetongue virus, hemorrhagic disease, endothelium, thrombocytopenia, DIC, vitro, culture, simulation. This was done on Nov. 14, 2008 and included the years 1986 to present. No appropriate alternatives were identified that would not compromise scientific objectives. However, the fewest number of animals was used to try to answer our questions, animals were tranquilized for procedures, and animals were euthanized if clinical signs met pre-established endpoint criteria.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CRF) title number and the specific section number (e.g., APHIS, 9 CFR 113,102):**

Agency _____ CFR _____

Column E Explanation

1. **Registration Number:** 57-R-0005 (The University of Georgia, Office of the Vice President for Research)
2. **Number of animals used in this study:** 21
3. **Species of animals used in this study:** degus (*Octodon degus*)
4. **Explanation of the procedure producing pain and/or distress.**

Degus were intraperitoneally inoculated with 5×10^5 trypomastigotes of *T. cruzi* I of Virginia opossum origin, *T. cruzi* IIa of raccoon origin, and the Brazil strain of *T. cruzi* (*T. cruzi* I). Infection status was followed over 45 days at which time the degus were euthanized and necropsied.

This protocol had a category C level because we thought some animals may develop clinical signs of Chagas disease (lethargy, weight loss, ruffed coat, etc.). However, throughout the course of the study we did not observe any clinical signs or weight loss. Animals acted healthy and appeared normal at the conclusion of the study. No gross lesions were noted on necropsy, but mild inflammation was observed in various tissues upon histological examination.

5. **Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

A literature search was conducted for refinement, replacement, or reduction opportunities in compliance with USDA policy #12. No appropriate alternatives were identified that would not compromise scientific objectives. Attempts to alleviate pain or discomfort would likely interrupt the natural progression of clinical signs and interfere with the study. We used endpoint score sheets as guidance to determine when animals should be euthanized rather than maintained in a progressively ill condition.

There was no pain or distress observed.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113,102):**

Agency _____ CFR _____

Column E Explanation

1. **Registration Number:** 57-R-0005 (The University of Georgia, Office of the Vice President for Research)
2. **Number of animals used in this study:** 49
3. **Species of animals used in this study:** ferret
4. **Explanation of the procedure producing pain and/or distress.**

Ferrets were intranasally administered influenza virus. Prior to inoculation, animals were identified with a unique microchip, which can also provide temperature data and blood samples were obtained. Only animals with a negative titer against influenza virus ($\leq 1:40$ by hemagglutination inhibition assay) were used. After infection, ferrets were monitored at least twice daily for clinical symptoms including fever, weight loss, and lethargy. Additionally, nasal washes were collected approximately every other day to measure virus titer. In all cases, virus was cleared within 7 days of infection. Fourteen or 21 days later, serum and nasal washes were collected and analyzed for influenza specific antibody responses. The ferrets along with samples of each serve to develop new vaccines and vaccine delivery tools for licensed influenza vaccines. Moreover these studies contribute to the overall scientific knowledge on the pathogenesis of and vaccination against influenza viruses.

5. **Scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

The use of analgesics or steroids to relieve pain have well-documented anti-inflammatory effects, which can also alter immunologic responses (i.e. vaccination). The main purpose of these studies is to better understand and improve upon influenza vaccination. Ferrets are considered the most appropriate animal model for studies of influenza virus infection, pathogenesis, transmission, and vaccination. Any alteration in the immune response of infected animals would alter the outcomes and invalidate the study. During acute infection, ferrets were given supportive care and monitored using strict criteria for humane euthanasia. At no time did animals in these studies demonstrate significant distress or require euthanasia because of disease caused by influenza infection.

A literature search was conducted for refinement, replacement, or reduction opportunities in compliance with USDA policy #12. No appropriate alternatives were identified that would not compromise scientific objectives.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CRF) title number and the specific section number (e.g., APHIS, 9 CFR 113,102):**

Agency _____ CFR _____